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MAUDE Adverse Event Report: EPIC SYSTEMS CORPORATION EPIC EHR EPIC SOFTWARE TRANSMISSION AND STORAGE

CDRH SuperSearch

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EPIC SYSTEMS CORPORATION EPIC EHR EPIC SOFTWARE TRANSMISSION AND STORAGE

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Event Date 06/10/2017
Event Type Malfunction
Event Description

There was a misidentification of the primary and private physician of this case that resulted in pt info and data being sent to the wrong physician, and a delay in it being distributed to the correct care team. Not only is this a hipaa violation, but it delays care upon transition from hospital. The ehr renders it difficult, if not impossible to, correct the error that populates many fields.

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Brand NameEPIC EHR
Type of DeviceEPIC SOFTWARE TRANSMISSION AND STORAGE
Manufacturer (Section D)EPIC SYSTEMS CORPORATION
Verona WI 53593
MDR Report Key6642848
Report NumberMW5070405
Device Sequence Number1
Product CodeMMH[24]
Report Source Voluntary
Reporter Occupation Physician
Report Date06/13/2017
1 Device Was Involved in the Event
1 Patient Was Involved in the Event
Date FDA Received06/13/2017
Is This An Adverse Event Report?No
Is This A Product Problem Report?Yes
Device Operator Health Professional
Was Device Available For Evaluation?Yes
Is The Reporter A Health Professional?Yes
Was the Report Sent to FDA?
Event Location No Information
Was Device Evaluated By Manufacturer?
Is The Device Single Use?
Is this a Reprocessed and Reused Single-Use Device?No
Type of Device Usage

Patient TREATMENT DATA
Date Received: 06/13/2017 Patient Sequence Number: 1

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2. http://www.addthis.com/bookmark.php

3. http://www.fda.gov/default.htm

4. https://www.fda.gov/MedicalDevices/default.htm

5. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm

6. /scripts/cdrh/devicesatfda/index.cfm

7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm

8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm

9. /scripts/cdrh/cfdocs/cfRL/rl.cfm

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17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm

18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm

19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm

20. /scripts/cdrh/cfdocs/cfClia/Search.cfm

21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm

22. https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm

23. https://www.accessdata.fda.gov/scripts/medwatch/

24. ../cfPCD/classification.cfm?start_search=&ProductCode=MMH

Page Last Updated: 01/31/2019

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